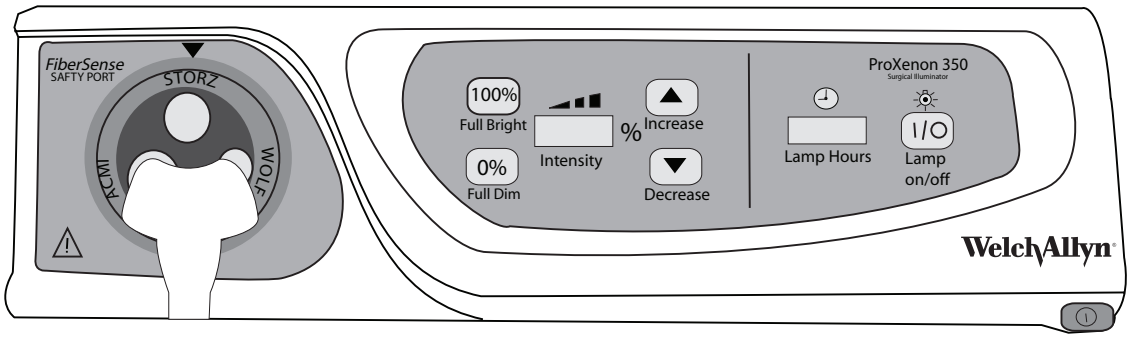
ProXenon 350 Surgical Illuminator



Directions for Use

REF 902 Series

WelchAllyn®

Advancing Frontline Care™

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1 Introduction

The Welch Allyn ProXenon 350 Surgical Illuminator is designed for use with the Welch Allyn ProXenon Headlight and Fiber system. The ProXenon 350 Surgical Illuminator uses a Welch Allyn high-intensity, narrow-beam, rugged xenon, short arc lamp with a fixed internal reflector to produce a uniform profile beam.

Safety features include an interlock sensor that blocks light output unless a fiberoptic cable is inserted in the working port; an overheating shut-off; and a safety interlock door switch to prevent accidental electrical shock while changing the lamp.

The Four Port Turret accepts Wolf, Storz, Olympus, and ACMI fiberoptic cables. Each port is readily identified on the turret perimeter.

Intended Use

The Surgical Illuminator is designed for use with fiberoptic headlight systems. It will accept fiberoptic light guides for Wolf, Storz, Olympus, and ACMI instrumentation.

The Accessory Headlight is a passive luminaire that is illuminated by fiberoptic light and utilized to provide supplemental light for surgical and medical procedures.

Contraindication

This product is contraindicated for use in neonate transillumination, with rhinolaryngoscopes, ophthalmic procedures, photosensitive people, or people receiving photosensitizing agents (hematoporphyrin derivatives) within 3 months.

User Profile

Only qualified personnel should use the ProXenon 350 Surgical Illuminator.

Theory of Operation

Light Source

The ProXenon 350 Xenon light source is powered by filtered AC line power. The filtered power feeds the power supply board, which contains two major components, the 12VDC auxiliary supply, and the high voltage igniter board. The igniter board provides power for the 300W Xenon lamp and the auxiliary power provides for the balance of the light source components.

The control logic board controls lamp on/off, display, shutter and safety interlock functions. The user interfaces with the control logic board by means of the front panel membrane switch assembly.

Fans provide cooling to the lamp and power supply and are powered by the auxiliary supply. ProXenon 350 uses parallel air flow design so that both power supply and fan are cooled with ambient air.

The lamp module contains a custom 300W Xenon Cermax style lamp kernel with a large anode design for improved lumen maintenance and an integral parabolic reflector. The parabolic reflector collimates the light that is launched into a optical train. The optical train contains:

- a shutter which controls total light intensity
- an optical filter which attenuates UV and IR radiation
- a condenser lens which focuses the light energy onto the face of fiberoptic cable
- a sensor which detects the presence of a fiberoptic cable allowing the shutter to open

When the main power switch is depressed, power is supplied to the fans and displays. When the lamp on/off membrane switch is pressed, ignition pulses are directed to the Xenon arc lamp. If the lamp fails to start, the ignition pulses time-out. If the lamp ignites, the green LED indicator above the lamp on/off membrane switch illuminates. Pushing the on/off membrane switch again turns the lamp off. It is normal to hear a "clicking" sound as the igniter attempts to start the lamp.

When a fiberoptic cable is inserted into the active port of the turret, a sensor sends a signal to the microprocessor allowing the shutter to open to the preset intensity setting. When the fiber is removed, the shutter closes to full dim position attenuating all light output. The intensity display shows the intensity setting as a continuous display when a fiber is inserted and a flashing display when no fiber is present and the shutter is closed.

Headlight

The light is transmitted via total internal reflection through the fiberoptic cable to the luminaire optics.

The luminaire optics consists of a two-element condenser lens assembly, a two-element projector (objective) lens assembly, a mirror and an objective window. The light exiting the face of the fiberoptic cable is collected by the condenser lens assembly and imaged slightly forward of the projector lens. The iris is completely filled by the condenser lens ray fans and is imaged by the projector lens 406mm from the projector window surface. The illumination spot is approximately 120mm in diameter and yields about 800 lumens at full iris opening with the light source at full open shutter.

A Brief Discussion about Light Intensity, Heat, Surgical Light Sources and Surgical Headlights

It is sound practice to always use the lowest possible intensity setting required to achieve good visualization. The ProXenon 350 Surgical Illuminator uses extremely restrictive UV and IR filtering to virtually eliminate the transmission of non-visible light energy. More than ninety-eight percent of all the radiant energy emitted from the ProXenon headlight system is in the form of full-spectrum (white) visible light.

Heat from the lamp is not transmitted through the fiberoptic cable to the luminaire. The perception of warmth caused by concentrated high intensity light is the result of the

absorption of light into tissue and the conversion of that light energy to heat. Different tissues absorb and reflect different wavelengths of light. The combination of reflected wavelengths is what we perceive as color. If specific wavelengths of light are not reflected, they are absorbed, and that absorbed light energy is converted to heat. Regardless of the brand or type of light used, light energy in excess of that required for good visualization will contribute to tissue warming and therefore should be avoided.

Risk of Fire

There is serious risk of igniting fires if the energized fiberoptic cables are placed on flammable materials. Never disconnect a terminal device from an energized fiberoptic cable or place an energized terminal device on any flammable material.

Risk of Tissue Injury

High intensity light can cause burns to tissue even if the tip of the fiberoptic cable or attached terminal device is cool. Burns are caused by the absorption of light by tissue and the subsequent conversion of that light energy into thermal energy (heat). Full-thickness burns can be caused by prolonged exposure to concentrated light energy. Anesthetized patients and poorly perfused tissues are particularly susceptible to burn injuries via this mechanism.

Risk of Fiber Damage

The ProXenon 350 Surgical Illuminator produces very high levels of visible light and is optimized to power the Welch Allyn ProXenon Surgical Headlight. When using endoscopic or surgical headlight fibers without canes, lenses or fusing at the input end, irreparable fiber damage may result when the ProXenon Surgical Illuminator intensity level is set above 70% and total accumulated lamp hours are 100 hours or less.

The ProXenon headlight fiber uses fusing technology at the input end to eliminate the use of epoxy as is common in the traditional fiber manufacturing process. It is primarily this epoxy that burns and causes fiber damage when exposed to high intensity light energy.

Welch Allyn has tested different brands and types of fiberoptic cables for durability in the ProXenon 350 Surgical Illuminator. Damage was found to most fibers with exposed epoxy ends when the ProXenon 350 Surgical Illuminator intensity is set above 70% and the lamp has less than 100 hours of accumulated use. Fiberoptic cables that use fusing techniques, a cane, or a lens on the input end of the cable, show better tolerance to the intense visible light energy of the ProXenon 350 Surgical Illuminator. However, because Welch Allyn cannot control other manufacturer's materials or manufacturing processes, any brand or type of fiberoptic cable previously tested and shown to withstand the light energy of the ProXenon 350 Surgical Illuminator could fail if the manufacturer implements a change in process or material of said fiber. Therefore, Welch Allyn cannot attest to the survivability of any fiberoptic cable used in the ProXenon 350 Surgical Illuminator other than the 902 series ProXenon Headlight Fiber.

Symbols

The following symbols are associated with the ProXenon 350 Surgical Illuminator.

Safety Symbols

Identifies information within the manual to avoid injury.

Caution: consult accompanying documents.

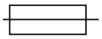
Alternating Current

Type BF Equipment

Recycling Symbol- Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply. See www.welchallyn.com/weee or contact Welch Allyn Customer Service.

Identifies information within the manual to avoid equipment failure.

Storage Humidity



Fuse

Dangerous Voltage

Equipotentiality.

Attention, Hot Surface

IPXØ Equipment is not protected against the ingress of liquid.

Transport Temperature

Consult accompanying documents.

Lamp

Button Symbols

Power ON/OFF

Lamp ON/OFF

100% Maximum light intensity

0% Minimum light intensity

Light intensity setting

Increases light intensity in 10% increments

Decreases light intensity in 10% increments

Lamp Hours

Agency Symbols

Medical electrical equipment with respect to electrical shock fire and mechanical hazards only in accordance with: UL60601-1 / CAN/CSA C22.2 NO.601.1

EMC Framework of Australia

The CE mark on this product indicates that it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive.

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Safety Warnings and Cautions

Familiarize all operating personnel with the general safety information in this summary. Specific warnings and cautions are also found throughout this manual. Such specific warnings and cautions may not appear in this summary.

Warnings

A warning statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to injury, illness, or death.

WARNING Only qualified personnel should use the ProXenon 350 Surgical Illuminator.

WARNING Before operating the ProXenon 350 Surgical Illuminator, read the Directions for Use. The ProXenon 350 Surgical Illuminator is a source of high electrical voltage, intense light, and heat. When used properly and with normal precautions, the ProXenon 350 Surgical Illuminator is a safe and effective light source.

WARNING RISK OF FIRE. Not suitable for use in the presence of a Flammable Anesthetic Mixture.

WARNING RISK OF SHOCK. The cover of the ProXenon 350 Surgical Illuminator should never be removed. Electrical shock hazard due to high internal voltage. There are no user serviceable parts inside this surgical illuminator except for the lamp and fuse which are accessible without removing the cover. Refer all service to Welch Allyn.

WARNING RISK OF SHOCK. Disconnect power cord before servicing.

WARNING This product comes with a power cord that is intended for use only with this product. The power cord has not been tested and approved for use with other products that may have the same power connectors. If you cannot locate the original power cord, please contact Welch Allyn to obtain replacement parts.

WARNING Before connecting the ProXenon 350 Surgical Illuminator to AC power, verify that the voltage to be applied is within the range specified on the identification label.

WARNING Extremely high energy light. It is the user's responsibility to check the specifications of any device attached to the ProXenon 350 Surgical Illuminator to verify that it can transmit the intense light output without generating high temperatures and heat build-up in the device that can cause serious burns.

WARNING Use only non-electrically conductive fiberoptic cables. Use of conductive fiberoptic cables will compromise the safety and effectiveness of this instrument.

WARNING High intensity light can cause burns to tissue even if the tip of the fiberoptic cable or attached terminal device is cool. Burns are caused by the absorption of light by tissue and the subsequent conversion of that light energy into thermal energy. Full-thickness burns can be caused by prolonged exposure to concentrated light energy. Anesthetized patients and poorly perfused tissues are particularly susceptible to burn injuries via this mechanism. There is serious risk of igniting fires if energized fiberoptic cables are placed on flammable materials. IT IS THE USER'S RESPONSIBILITY TO DETERMINE AND MAINTAIN THE MINIMUM SAFE DISTANCE BETWEEN THE END OF THE ENERGIZED fiberoptic CABLE AND ANY LIVING TISSUE OR FLAMMABLE MATERIAL.

WARNING Intense light emitted from the ProXenon 350 Surgical Illuminator can cause permanent eye damage if viewed directly with unprotected eye. The risk of injury is reduced by using the minimum level of illumination necessary, by minimizing exposure time, and by avoiding close stationary viewing.

WARNING There is a risk of injury to tissue from exposure to the intense illumination. Using light intensity settings in excess of that required for good visualization contributes to tissue warming and should be avoided.

WARNING Always have back-up light source available in case of failure during a procedure.

WARNING The lamp module and nearby structures become VERY HOT, even after brief operation. To prevent burns, turn off the ProXenon 350 Surgical Illuminator and allow it to cool for 10 minutes prior to removing lamp module.

WARNING When the ProXenon 350 Surgical Illuminator is on, never disconnect the fiberoptic cable from the terminal device. High intensity light from the end of the fiberoptic cable can ignite flammable materials (for example, drapes) or cause burns to tissue.

WARNING Replace fuses as marked. See Fuse Replacement Section.

WARNING Do not use for neonate transillumination. Erythema may result.

WARNING Ensure that active port of the Four-Port Turret is positioned correctly and the fiberoptic cable is fully seated.

WARNING The ProXenon 350 Light Source has been evaluated for use as a Headlight System light source only. The safety and effectiveness of this light source for endoscopic use has not yet been evaluated.

Cautions

A caution statement in this manual identifies a condition or practice, which if not corrected or discontinued immediately, could lead to equipment failure, equipment damage, or data loss.

Caution Rx Only: United States Federal Law restricts this device to sale by or on the order of a health care practitioner.

Caution Do not touch or change lamp module immediately after operation. Allow lamp to cool 10 minutes.

Caution Since the ProXenon 350 Surgical Illuminator uses a custom lamp module, always have a spare lamp module available for replacement. Use only Welch Allyn replacement lamp module REF 90209.

Caution To prevent damage to the ProXenon 350 Surgical Illuminator, prevent overheating, and maintain the warranty, replace lamp only with Welch Allyn REF 90209 lamp module. Read instructions before replacing lamp module.

Caution Grounding reliability is achieved only when connected to hospital-use or hospital-grade receptacles. Inspect electrical plug and cord routinely. Do not use if damaged.

Caution PROVIDE VENTILATION TO PREVENT OVERHEATING. Keep cooling vents free from obstructions. Do not cover or drape the ProXenon 350 Surgical illuminator. Provide a 6 inch (15.24 cm) distance between the ProXenon 350 Surgical Illuminator and any solid objects. Use the ProXenon 350 Surgical Illuminator only when it is in the horizontal position.

Caution Do not use the turret as a light attenuator or operate with the turret misaligned with the light port.

Caution The metal end of the fiberoptic cable gets hot during use. Allow to cool before touching.

Caution IPXØ - Equipment not protected against the ingress of water. Do not use or store liquids above or on the surgical illuminator.

Caution The ProXenon 350 Surgical Illuminator produces very high levels of visible light and is optimized to power the Welch Allyn ProXenon Headlight and Fiber. When using endoscopic or surgical headlight fibers without canes, lenses, or fusing at the input end, irreparable fiber damage will result when the ProXenon 350 Surgical Illuminator intensity level is set above 70% and total accumulated lamp hours are 100 hours or less.

Caution When using fibers other than the 902 series ProXenon headlight fiber, do not exceed 70% intensity setting when total accumulated lamp hours are less than 100.

Caution Do not operate the ProXenon 350 Surgical Illuminator without a lamp module installed.

Caution The ProXenon 350 meets the Class A requirements of IEC 60601-1-1-2 regarding incidental emission of radio frequency interference. As such it is suitable for use in commerical grade electrical environments. If the ProXenon 350 is used in residential grade electical environments and you experience incidental interference with other equipment that uses radio frequency signals to operate, minimize the interference as described under "Electromagnetic Compatibility" on page 25.

Avertissements et précautions d'usage

Informer les utilisateurs des précautions générales à prendre, résumées ci-dessous. Ce manuel comprend également des avertissements et précautions spécifiques. Il est possible que ces avertissements et précautions spécifiques ne soient pas indiqués dans ce résumé.

Avertissements

Les avertissements de ce manuel identifient les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des blessures, des maladies ou éventuellement entraîner la mort.

AVERTISSEMENT Seul du personnel qualifié doit utiliser l'illuminateur chirurgical ProXenon 350.

AVERTISSEMENT Lire le mode d'emploi avant d'actionner l'illuminateur chirurgical ProXenon 350. L'illuminateur chirurgical ProXenon 350 est une source de tension électrique élevée, de lumière intense et de chaleur. Utilisé correctement et en respectant les précautions d'usage normales, l'illuminateur chirurgical ProXenon 350 est une source lumineuse sûre et efficace.

AVERTISSEMENT RISQUE D'INCENDIE. Ne convient pas pour une utilisation en présence de mélange anesthésique inflammable.

AVERTISSEMENT RISQUE DE CHOC ÉLECTRIQUE. Ne jamais retirer le couvercle de l'illuminateur chirurgical ProXenon 350. Risque de choc électrique dû à la tension interne élevée. Aucune pièce située à l'intérieur de cet illuminateur chirurgical ne peut être réparée par l'utilisateur, à l'exception de la lampe et des fusibles qui sont accessibles sans enlever le couvercle. Pour toute procédure d'entretien, consulter Welch Allyn.

AVERTISSEMENT RISQUE DE CHOC ÉLECTRIQUE. Déconnecter le cordon d'alimentation avant l'entretien.

AVERTISSEMENT Ce produit est livré avec un cordon d'alimentation qui est conçu pour une utilisation uniquement avec ce produit. Le cordon d'alimentation n'a pas été testé et approuvé pour une utilisation avec d'autres produits ayant les mêmes connecteurs d'alimentation. En cas de perte du cordon d'alimentation d'origine, contacter Welch Allyn pour en obtenir un autre.

AVERTISSEMENT Avant de connecter l'illuminateur chirurgical ProXenon 350 sur le secteur, vérifier que la tension devant être appliquée se situe dans la plage spécifiée sur l'étiquette d'identification.

AVERTISSEMENT Lumière à très haute énergie. L'utilisateur est responsable de la vérification des caractéristiques de tout dispositif relié à l'illuminateur chirurgical ProXenon 350 afin de s'assurer qu'il peut transmettre la luminosité intense sans générer des températures élevées ou accumuler de la chaleur dans l'appareil susceptible d'être à l'origine de graves brûlures.

AVERTISSEMENT Utiliser uniquement des câbles à fibres optiques non conducteurs. L'utilisation de câbles à fibres optiques conducteurs compromettra la sécurité et l'efficacité de cet instrument.

AVERTISSEMENT La lumière haute intensité peut causer des brûlures au niveau des tissus, même si l'extrémité du câble à fibres optiques ou la borne connectée est froide. Les brûlures sont causées par l'absorption de lumière par les tissus et la conversion par la suite de cette énergie lumineuse en énergie thermique. Des brûlures du troisième degré peuvent être causées du fait d'une exposition prolongée à une énergie lumineuse concentrée. Les patients anesthésiés et les tissus mal perfusés sont particulièrement susceptibles de subir des brûlures via ce mécanisme. Il existe un risque important d'incendie si des câbles à fibres optiques sous tension sont placés sur des matériaux inflammables. IL INCOMBE À L'UTILISATEUR DE DÉTERMINER ET DE MAINTENIR LA DISTANCE DE SÉCURITÉ MINIMUM ENTRE L'EXTRÉMITÉ DU CÂBLE À FIBRES OPTIQUES SOUS TENSION ET TOUT TISSU VIVANT OU MATÉRIAU INFLAMMABLE.

AVERTISSEMENT La lumière intense émise depuis l'illuminateur chirurgical ProXenon 350 peut endommager définitivement les yeux si elle est regardée directement sans protection oculaire. Le risque de blessure est réduit en utilisant le niveau minimum d'illumination nécessaire, en minimisant le temps d'exposition et en évitant toute visualisation fixe à proximité.

AVERTISSEMENT L'exposition à l'illumination intense génère un risque de lésions tissulaires. Quel que soit le type et la marque de lumière utilisés, éviter d'utiliser des paramètres d'intensité lumineuse supérieurs à ceux requis pour une bonne visualisation car cela contribue au réchauffement des tissus.

AVERTISSEMENT Toujours garder à proximité une source lumineuse de secours afin de parer à une panne éventuelle en cours d'intervention.

AVERTISSEMENT Le module de lampe et les structures avoisinantes deviennent TRÈS CHAUDS, même après une intervention de courte durée. Pour éviter toute brûlure, éteindre l'illuminateur chirurgical ProXenon 350 et le laisser refroidir pendant 10 minutes avant de retirer le module de lampe.

AVERTISSEMENT Lorsque l'illuminateur chirurgical ProXenon 350 est sous tension, ne jamais déconnecter le câble à fibres optiques de la borne. La lumière haute intensité issue de l'extrémité du câble à fibres optiques peut mettre le feu à des matériaux inflammables (par exemple, des champs opératoires) ou entraîner des brûlures au niveau des tissus.

AVERTISSEMENT Remplacer les fusibles comme indiqué. Voir la section de remplacement des fusibles.

AVERTISSEMENT Ne pas utiliser pour la transillumination chez le nouveau-né. Un érythème peut surgir.

AVERTISSEMENT S'assurer que le port actif de la tourelle à quatre ports est positionné correctement et que le câble à fibres optiques est bien en place.

AVERTISSEMENT L'illuminateur ProXenon 350 a été évalué comme illuminateur du module de lampe frontale uniquement. La sûreté et l'efficacité pour un usage endoscopique n'ont pas, à ce jour, été évaluées.

Mises en garde

Dans ce manuel, une mise en garde identifie les conditions ou pratiques qui, si elles ne sont pas corrigées ou arrêtées immédiatement, risquent de provoquer des pertes de données, un endommagement ou une défaillance du matériel.

Mise en garde Sur prescription uniquement : en vertu de la loi fédérale des États-Unis, ce produit ne peut être vendu que par un médecin ou sur prescription médicale.

Mise en garde Ne pas toucher ou modifier le module de lampe immédiatement après une intervention. Laisser la lampe refroidir pendant 10 minutes.

Mise en garde Du fait que l'illuminateur chirurgical ProXenon 350 utilise un module de lampe personnalisé, toujours garder à disposition un module de lampe de rechange pour un remplacement éventuel. Utiliser uniquement le module de lampe de rechange Welch Allyn RÉF. 90209.

Mise en garde Pour éviter d'endommager l'illuminateur chirurgical ProXenon 350, éviter de surchauffer et conserver la garantie, ne remplacer la lampe que par le module de lampe Welch Allyn RÉF. 90209. Lire les instructions avant de remplacer le module de lampe.

Mise en garde La mise à la masse ne peut être fiable que lors d'une connexion sur des prises d'utilisation ou de qualité hospitalière. Inspecter régulièrement les prises et cordons électriques. Ne pas utiliser s'ils sont endommagés.

Mise en garde POUR ÉVITER TOUTE SURCHAUFFE, PRENDRE SOIN DE BIEN AÉRER. Ne pas boucher les orifices d'aération. Ne pas couvrir ou draper l'illuminateur chirurgical ProXenon 350. Laisser un espace de 15,24 cm (6 pouces) entre l'illuminateur chirurgical ProXenon 350 et tout objet solide. Utiliser l'illuminateur chirurgical ProXenon 350 uniquement lorsqu'il est en position horizontale.

Mise en garde Ne pas utiliser la tourelle pour atténuer la lumière ni opérer avec la tourelle non alignée sur le port de la lumière.

Mise en garde L'extrémité métallique du câble à fibres optiques chauffe en cours d'utilisation. Laisser refroidir avant de toucher.

Mise en garde IPXØ - L'appareil n'est pas étanche. Ne pas utiliser ou stocker de liquides au-dessus de l'illuminateur chirurgical, ou sur ce dernier.

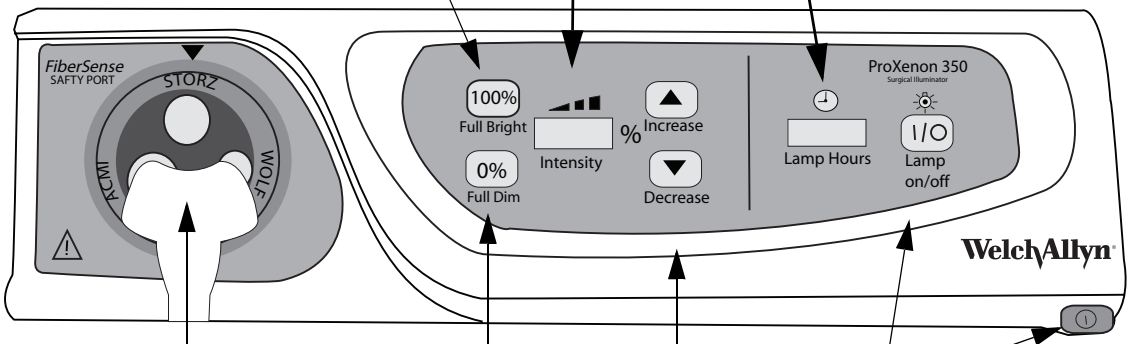
Mise en garde L'illuminateur chirurgical ProXenon 350 produit des niveaux très élevés de lumière visible et est optimisé pour alimenter la lampe frontale et fibre ProXenon de Welch Allyn. Lors de l'utilisation de fibres de lampes frontales chirurgicales ou endoscopiques sans tiges, lentilles ou fusion au niveau de l'entrée, les fibres subissent des dommages irréversibles lorsque le niveau d'intensité de l'illuminateur chirurgical ProXenon 350 est supérieur à 70 % et que le nombre total cumulé d'heures d'utilisation de la lampe est inférieur ou égal à 100.

Mise en garde Lors de l'utilisation de fibres autres que la fibre pour lampe frontale ProXenon série 902, ne pas dépasser une intensité de 70 % lorsque le nombre total cumulé d'heures de fonctionnement de la lampe est inférieur à 100.

Mise en garde Ne pas utiliser l'illuminateur chirurgical ProXenon 350 sans qu'un module de lampe soit installé.Le ProXenon 350 répond aux exigences de classe A de la norme CEI 60601-1-1-2 relative à l'émission accidentelle d'interférences de radiofréquences. En tant que tel, son utilisation est adaptée aux environnements électriques de qualité commerciale. Si le ProXenon 350 est utilisé dans des environnements électriques de qualité résidentielle et si des interférences accidentelles se produisent avec d'autres équipements qui font appel aux radiofréquences pour fonctionner, réduire les interférences comme indiqué dans la section "Electromagnetic Compatibility" on page 25.

2 Controls and Function

Front Panel Functions



Full Bright: quick command to set brightness to 100%.

Intensity Setting- displays light output level setting in 10% increments.

Lamp Hours: accumulated lamp hours since last reset.

Power button: Main power ON/OFF.

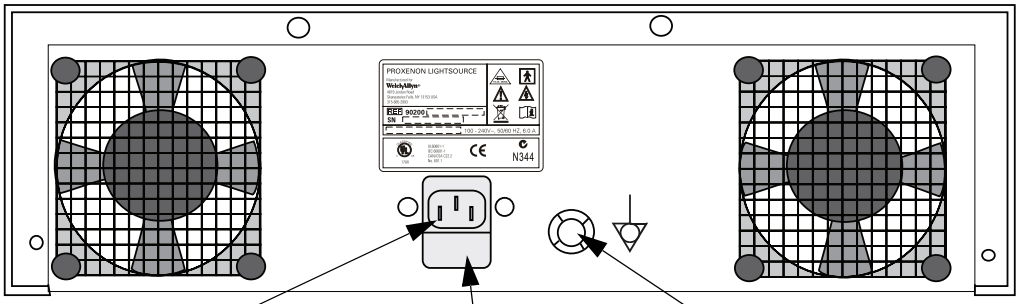
Full Dim: quick command to set brightness to 0%.

Lamp ON/OFF button: turns the lamp on or off after powering the system.

Four-Port Turret: accepts ACMI, Olympus, Storz, or Wolf fiberoptic cables. The port names are visible on the perimeter of the adapter outboard from the port inputs.

Brightness Control: increases or decreases light output levels in 10% increments.

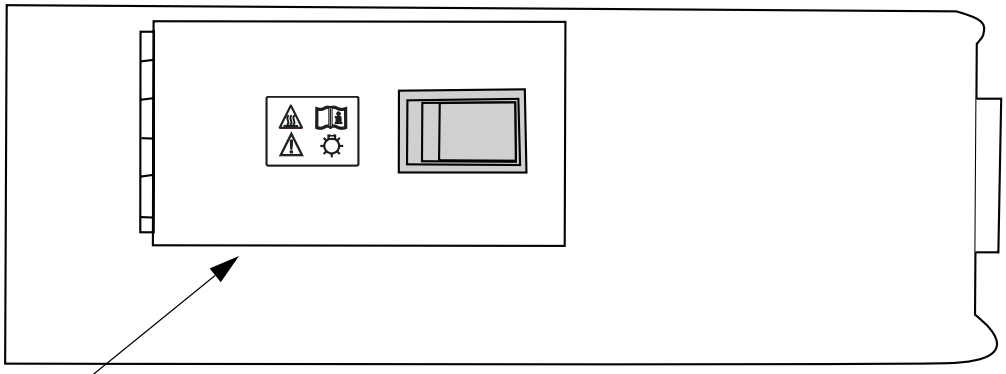
Back and Side Panel Functions



AC Input Power Receptacle: Three-prong receptacle that accepts an AC power cord

Fuse Drawer: contains two 6.3 amp main fuses.

Equipotentiality Stud



Lamp Module Access Door: access for Lamp Module replacement.

3 Operation

WARNING Only qualified personnel should use the ProXenon 350 Surgical Illuminator.

WARNING Intense light emitted from the ProXenon 350 Surgical Illuminator can cause permanent eye damage if viewed directly with unprotected eye. The risk of injury is reduced by using the minimum level of illumination necessary, by minimizing exposure time, and by avoiding close stationary viewing.

Unpack the ProXenon 350 Surgical Illuminator and accessories. Retain the shipping materials in the event of shipping damage or return, if necessary, to Welch Allyn for repair or warranty service.

1. Place the ProXenon 350 Surgical Illuminator on a horizontal supporting surface. Allow 6 inches of open space to the rear of the unit so that the cooling airflow is not restricted.
2. Attach power cord retainer if desired (included).
3. Connect the hospital-grade power cord into the receptacle of the ProXenon 350 Surgical Illuminator.
4. Rotate the Turret to select the desired port. Verify that Turret clicks into place and the line corresponding to the desired port aligns with the arrow on the light source.
5. Insert the fiberoptic cable into the port until it is fully seated.
6. Press the **Power** button until you hear a "click." Release the button and the power symbol illuminates. The system is energized and activates the cooling fans and displays.
7. Press the **Lamp ON/OFF** button to ignite the lamp. The green LED flashes until lamp ignition occurs then the LED stays lit until the lamp is turned off. The Intensity Setting displays the last level used.

Note A fiberoptic cable is necessary for light output. If the fiberoptic cable is not connected, the shutter closes and the Intensity Setting flashes.

8. Press the **Full Bright** button to attain 100% of total available light or press the **Full Dim** button to completely attenuate light output. Use the **Increase** or **Decrease Brightness Control** buttons to adjust the available light output in 10% increments.

Caution When using fibers other than the 902 series ProXenon headlight fiber, do not exceed 70% intensity setting when total accumulated lamp hours are less than 100.

To shut down:

1. Press the **Lamp ON/OFF** button to extinguish the lamp. The lamp LED fades out.
2. Press the **Power** button to cycle the power off. The power symbol fades and power is cut from the system. It is normal for the system to continue running for a few seconds after the power is cycled off.

Note When possible, allow the fans to run for at least one minute after the lamp is extinguished. This allows the fans to cool the ProXenon 350 Surgical Illuminator and extends the service life.

4 Care and Maintenance

Basic Troubleshooting

Symptom	Possible Problem	Remedy
No power.	Power cord is not plugged into receptacle at the instrument or into the hospital grade outlet.	Plug in power cord.
	ON/OFF button is off.	Press the Main ON/OFF button.
	Fuse is blown.	Replace fuse. See Fuse Replacement page 18.
	Lamp module is installed incorrectly.	Re-install lamp module correctly. See Lamp Care and Replacement page 18
	Lamp door is not closed tightly.	Close lamp door completely.
	Internal power supply not operating.	Return the ProXenon 350 Surgical Illuminator to Welch Allyn. Contact your local Welch Allyn Technical Service Center listed on page ii.
No light output.	Lamp is at the end of service.	Replace lamp module.
	Lamp module is installed incorrectly.	Re-install lamp module correctly. See Lamp Care and Replacement page 18.
	Lamp door is not closed tightly.	Close lamp door completely.
	Fiberoptic cable not connected.	Shutter is not attenuated. Connect fiberoptic cable.
	Fiberoptic cable is not fully seated.	Push the fiberoptic cable in completely.
	Fiberoptic cable is worn or damaged	Replace fiberoptic cable.
	Turret misaligned.	Align Turret correctly. See Operation page 15.
Xenon lamp flickers or dims.	Lamp is nearing end of service.	Replace lamp module. See Lamp Care and Replacement page 18.
Field of view is dim.	Controls set incorrectly.	Adjust Full Bright or Full Dim controls appropriately.
	Lamp module is installed incorrectly.	Re-install lamp module correctly. See Lamp Care and Replacement page 18.
	Fiberoptic cable is worn or damaged.	Replace fiberoptic cable.
	Turret misaligned.	Align Turret correctly. See Operation page 15
Turns off after a few minutes of operation.	Obstructed air intake; overheating causes thermal switch to trip.	Allow instrument to cool (10 minutes). Remove obstruction(s).
	Fan not running; overheating causes thermal switch to trip.	Contact your local Welch Allyn Technical Service Center listed on page ii.

Fuse Replacement

WARNING RISK OF SHOCK. Disconnect power cord before servicing.

1. Unplug the power cord.
2. Remove the fuse cover with a flat blade screwdriver.
3. Replace the blown fuse(s) with the same size and rating (6.3A time delay: T6.3A, 250V AC fuses, size 5 x 20 mm).
4. Re-install the fuse cover.
5. Reconnect the power cord.
6. Press the **Power** button to apply power until you hear a "click" and power symbol illuminates.

Note If the ProXenon 350 Surgical Illuminator fails to operate properly again, contact Welch Allyn for repair (listed on page ii.)

Lamp Care and Replacement

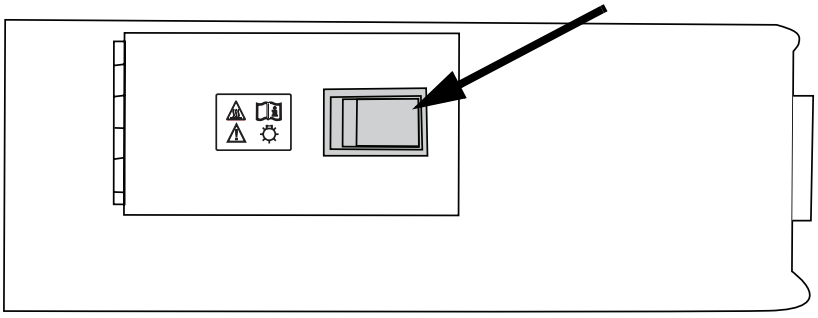
WARNING The lamp module and nearby structures become VERY HOT, even after brief operation. To prevent burns, turn off the ProXenon 350 Surgical Illuminator and allow it to cool for 10 minutes prior to removing lamp module.

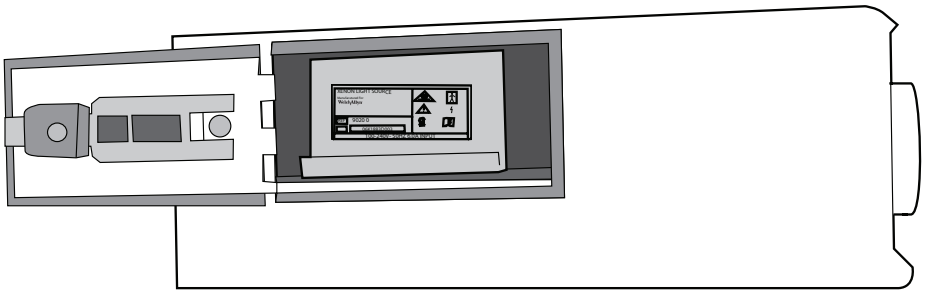
Caution Do not use the ProXenon 350 Surgical Illuminator without a lamp module installed.

Replace the lamp under any of the following conditions: accumulated usage of more than 650 hours, an increasing number of ignition attempts required to ignite lamp, failure of lamp to start, or low light output.

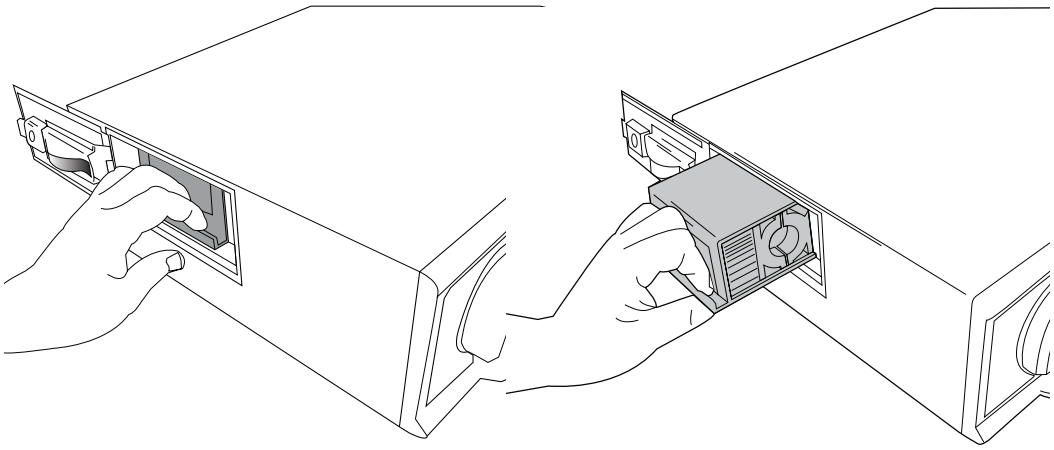
To remove the lamp module:

1. Turn ProXenon 350 Surgical Illuminator off (see page 16) and unplug the power cord.
2. Wait 10 minutes to allow the lamp to cool.
3. Unlatch and open the access door located on the side of the ProXenon 350 Surgical Illuminator.





4. Grasp the handle and pull the entire lamp module out of the ProXenon 350 Surgical Illuminator.



To insert a new lamp module:

Caution Do not touch the face of the lamp (glass window).

1. Orient the new lamp module so that the window of the Welch Allyn lamp REF 90209 is facing the front of the ProXenon 350 Surgical Illuminator.
2. Align the sides of the lamp module and place it in the receiver channel. Firmly push in the lamp module to ensure proper connection.
3. Close and latch the door. If the door does not close completely, the lamp module is not fully seated.

To Reset the Lamp Hours Meter:

1. Verify that the lamp is off.
2. Press and hold the **Full Dim + Decrease** buttons.
3. While holding the **Full Dim + Decrease** buttons**,** press and hold the **Lamp ON/OFF** buttons for three seconds. The **Lamp Hour** window flashes three times and resets to zero.

Note To cancel reset, release any button during the three-second period.

Cleaning Instructions

Caution Do not expose the ProXenon 350 Surgical Illuminator to autoclaving or any cleaning/sterilization process involving excessive heat or moisture. This could lead to damage and void the warranty.

Caution To reduce risk of electric shock, do not remove cover. Refer servicing to qualified personnel. No cleaning of any interior components is required.

Caution Use hospital approved disinfectants (e.g., 10% clorox/90% water solution).

Caution Never introduce any liquid directly to the surface of the ProXenon 350 Surgical Illuminator.

Wipe the surface of the ProXenon 350 Surgical Illuminator periodically with a damp, soft cloth using isopropyl alcohol or a mild detergent solution to remove surface contamination. Allow the instrument to dry before use.

Transportation and Storage

- Ship the ProXenon 350 Surgical Illuminator only in original packing materials.
- When using a load-carrying platform of a cart, truck, or in the trunk of an automobile, place the ProXenon 350 Surgical Illuminator on its feet. Remove the AC power cord and the fiberoptic cable.
- When hand-carrying the ProXenon 350 Surgical Illuminator, hold it firmly with both hands. Verify that the AC power cord and the fiberoptic cable are both removed from the instrument.
- DO NOT severely bend, apply excessive force, pull, twist, or squeeze the AC power cord. Wind the AC power cord loosely.
- DO NOT subject the ProXenon 350 Surgical Illuminator to excess impact as this may cause the instrument to malfunction.

DO NOT expose the ProXenon 350 Surgical Illuminator to direct sunlight or high temperatures.

Service

Caution Unauthorized repairs will void the warranty.

A Welch Allyn Service Center must perform all repairs on products under warranty. Qualified electronics personnel or a Welch Allyn Service Center should repair products out of warranty.

Technical Assistance

If you have an equipment problem that you cannot resolve, call the Welch Allyn Service Center nearest you for assistance. Technical service telephone support is available on normal business days.

If you are advised to return a product to Welch Allyn for repair or routine maintenance, schedule the repair with the service center nearest you.

Before returning a product for repair, you must obtain authorization from Welch Allyn. Service personnel will give you a Service Notification number. Please note this number on the outside of your shipping box. Returns without a Service Notification number will not be accepted for delivery.

Parts and Components

For best results, use only approved Welch Allyn equipment.

90209	Lamp Module
90260	US Power Cord, 15 ft
90261	S. Africa/India Power Cord, 8 ft
90262	Continental Europe Power Cord, 15 ft
90263	Israel Power Cord, 8 ft
90264	UK Power Cord, 15 ft
90265	Denmark Power Cord, 8ft
90266	Australia Power Cord, 15 ft

Accessories

90250	ProXenon Mobile Stand

5 Specifications

Electrical Input

Input Voltage	100 - 240 VAC, 50/60Hz universal, 6.0A input
AC Power Connector	Located on rear panel, dual fuses
Line Cord	IEC 60320
Fuse	250 VAC T6.3A, 5 x 20 mm

Performance

Light Output	2380 Lumens nominal initial output through 3mm glass rod at full rated power. Spectral output 380 - 750nm nominal.
Over-temperature Protection	Automatic shut down to prevent overheating.
Over Heat Recovery / Auto Cool	Fans will remain on if thermal shut down occurs when power is ON. Use Lamp ON / OFF button to re-ignite lamp.
FiberOptic Connection Safety Feature	Output shutter will not open unless a fiberoptic cable is fully inserted into the active port on the turret. Output shutter will fully close if fiberoptic cable is removed from active port. Intensity Setting flashes during this status
Lamp Power Supply	PS300-12 type
Lamp Module	Welch Allyn 300 Watt Xenon REF 90209.
Lamp Module Replacement	Access via latched hinged door.
Lamp Life	650 hours to 50% of initial output specification measured through 3mm glass rod.

Mechanical and Environmental

Dimensions	Height 12.98 cm (5.1") x Width 43 cm (16.9") x Depth 38.15 cm (15.0") (approx)
Weight	9.75 kg (21.5 lbs.)
Operating Temperature	6° C to 40° C (43° F to 104° F)
Storage Temperature	-25° C to +55° C (-13° F to + 131° F)
Operating and Storage Humidity	10 - 85% relative humidity, non-condensing
Operating Pressure	1013 hPa ± 170 hPa
Audible Noise	<45 dB per ISO 7779 bystander measurement method
Shipping, Shock and Vibration	per ISTA 1A
Safety, EMC, and regulatory compliance	CAN/CSA C22.2 No. 601.1 CAN/CSA C22.2 No. 601.1.2 UL 60601-1 IEC/EN 60601-1 IEC/EN 60601-1-2

Classification

Class 1	Relies upon the connection to the protective earth conductor of the installation to prevent shock hazards.
Type BF	Applied part is floating from earth.
IPXØ	No protection against the ingress of liquids.
Mode Of Operation	Suitable for continuous operation.
Flammable	Not suitable for use in the presence of a Flammable Anesthetic Mixture

CLASSIFIED UL C US

Medical electrical equipment with respect to electrical shock fire and mechanical hazards only in accordance with: UL60601-1 / CAN/CSA C22.2 NO.601.1

Electromagnetic Compatibility

WARNING AC cables other than those specified by manufacturer may result in increased EMISSIONS or decreased IMMUNITY.

Electromagnetic Emissions

The Welch Allyn ProXenon 350 Surgical Illuminator is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn ProXenon 350 Surgical Illuminator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Welch Allyn ProXenon 350 Surgical Illuminator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Welch Allyn ProXenon 350 Surgical Illuminator is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The Welch Allyn ProXenon 350 Surgical Illuminator is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn ProXenon 350 Surgical Illuminator should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Welch Allyn ProXenon 350 Surgical Illuminator requires continued operation during power mains interruptions, it is recommended that the Welch Allyn ProXenon 350 Surgical Illuminator be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Immunity

The Welch Allyn ProXenon 350 Surgical Illuminator is intended for use in the electromagnetic environment specified below. The customer or user of the Welch Allyn ProXenon 350 Surgical Illuminator should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn ProXenon 350 Surgical Illuminator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = (1.17)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = (1.17)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.33)\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Welch Allyn ProXenon 350 Surgical Illuminator is used exceeds the applicable RF compliance level above, the Welch Allyn ProXenon 350 Surgical Illuminator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Welch Allyn ProXenon 350 Surgical Illuminator.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Welch Allyn ProXenon 350 Surgical Illuminator

The Welch Allyn ProXenon 350 Surgical Illuminator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Welch Allyn ProXenon 350 Surgical Illuminator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn ProXenon 350 Surgical Illuminator as recommended below, according to the maximum output power of the communications equipment.

	Separation Distance According to Frequency of Transmitter (m)		
Rated Max. Output Power of Transmitter (W)	**150 kHz to 80 MHz** $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.5 GHz** $d = (2.33)\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

6 Mobile Stand (Optional)

Retain the shipping materials in the event of shipping damage or return, if necessary, to Welch Allyn for repair or warranty service.

WARNING Verify that the two locking casters are in the unlocked position prior to movement.

WARNING Only qualified personnel should perform maintenance.

WARNING Do not use the mobile stand if defects are found.

WARNING Verify the power cord is properly placed to eliminate the risk of tripping during use.

Caution Verify that both casters are in the locked position to prevent inadvertent movement of the mobile stand.

Caution Always properly secure the power cord, headlight, and fiber cable prior to movement.

Caution To avoid tipping over the stand, verify that the mobile stand cannot roll over the power cord or headlight fibers.

Caution Only qualified personnel should assemble this product.

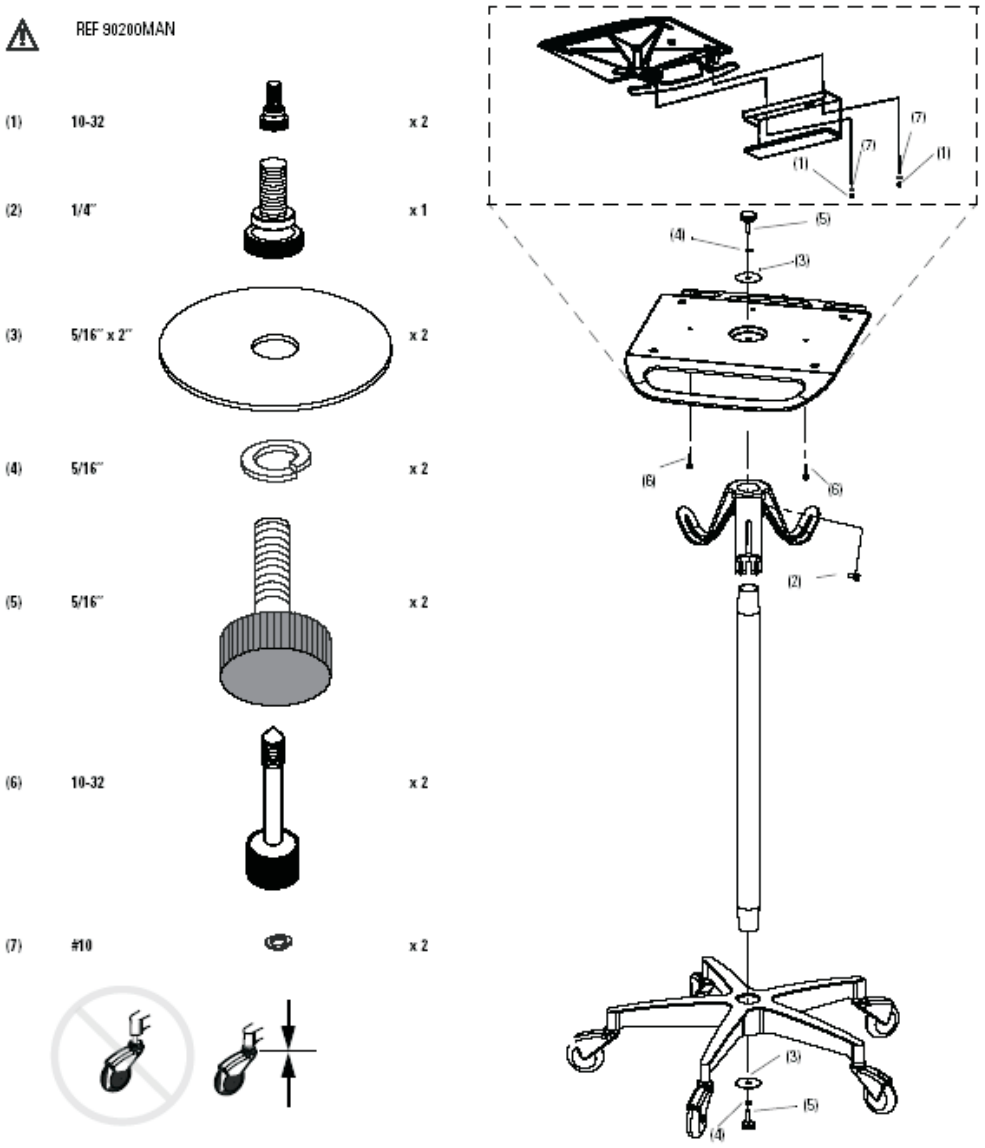
Caution Only use this mobile stand with the products listed within this manual. Do not use with any other products.

Caution Each hook of the hanger is designed to store 1 headlight/fiber assembly (3 total per mobile stand). Each hanger hook is designed to hold a maximum weight of 1 lb (453g) or one headlight and one fiber cable maximum. Do not load with any other equipment.

Caution Always follow the manufacturer's cleaning instructions.

Caution Avoid cleaners and/or disinfectants containing materials harmful to paints, metal, or plastics.

Assemble the ProXenon 350 Surgical Illuminator Mobile Stand



1. Unpack the Mobile Stand.
2. Insert the pole into the 5-leg base. Secure with a 5/16" thumbscrew, a 5/16" lock washer, and a flat washer.
3. Slide the hanger onto the pole. Secure with a 1/4" nylon thumbscrew.
4. Install the 10-32 captured thumbscrews onto the platform.
5. Place the platform on top of the pole. Secure with a 5/16" thumbscrew, a 5/16" lock washer, and a flat washer.
6. Install Coolvent Padset dispenser box (REF 90242) into holder.

Mounting the ProXenon Light Source

1. Lock the caster wheels to prevent stand movement.
2. Place the ProXenon 350 Surgical Illuminator (REF 902 series) on the platform so that the rubber feet rest in the platform wells. Position the light source so that the front of the light source is above the platform handle and the rear of the light source is above the cord wrap.
3. Secure the light source with two #10-32 captured thumbscrews. Wrap the power cord around the cord wrap located at the rear of the platform.

Maintenance of the Mobile Stand

Cleaning

Treat the mobile stand as a non-patient contact environmental surface. Wipe with a dampened cloth/wipe using a Quaternary-Amine/Low Alcohol Concentration Based combination low or intermediate level cleaner-disinfectant that is labeled compatible with metal, plastic, and painted surfaces.

Inspection

Periodically inspect the mobile stand for:

- proper operation of casters and locking casters
- secure connection between the pole to the base, platform, and hanger
- secure connection between the lightsource and the platform

Repair or replace the mobile stand if any defects are found prior to use.

Specifications

Storage	-20° C to 49° C @ 95% relative humidity, max.
Platform Height	915 mm
Base Diameter	584 mm

Warranty

Welch Allyn warrants the ProXenon 350 Surgical Illuminator, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of two years, exclusive of lamp and fuses. Welch Allyn warrants the REF 90209 lamp module to be free of defects in material and workmanship for a period of 6 months from the date of purchase from Welch Allyn or its authorized distributors or agents.

Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the ProXenon 350 Surgical Illuminator to Welch Allyn or an authorized distributor, agent, or service representative. Units must be returned with the lamp module installed.

This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping damage. Warranty is void if the instrument is not used in accordance with manufacturer's recommendations, if repaired by other than Welch Allyn or an authorized agent, or if other than Welch Allyn replacement lamp (REF 90209) is used. Purchase date determines warranty requirements. No other express warranty is given.

You must obtain a service notification number from Welch Allyn to return your Product before you send it to Welch Allyn's designated service center for repair. Contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

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Advancing Frontline Care™

Manual Order No. 90200MAN
Material No. 707224 Rev. F